Sublingual Immunotherapy

Goal(s):
- Restrict use of sublingual immunotherapy tablets for conditions funded by the OHP and where there is evidence of benefit. Treatment for allergic rhinitis is funded by the Oregon Health Plan only if there is a comorbidity such as asthma.
- Allow case-by-case review for members covered under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program.

Length of Authorization:
- Up to 12 months

Requires PA:
- All FDA-approved sublingual immunotherapy tablets (physician administered and pharmacy claims).

Covered Alternatives:
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. FDA-Approved Sublingual Immunotherapy Tablets

Product Name (BRAND NAME)	How Supplied	Approved Age Range	When to Initiate Therapy
Timothy Grass Pollen Allergen Extract (GRASTEK)	2,800 BAU tablet	5 to 65 yo	Start 12 weeks prior to expected onset of grass season and continue through grass season.
Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergy Extract (ORALAIR)	100 IR and 300 IR tablets		Start 16 weeks prior to expected onset of respective grass season and continue through grass season.
Short Ragweed Pollen Allergen Extract (RAGWITEK)	12 Amb a 1-Unit tablet		Start 12 weeks prior to expected onset of ragweed season and continue through ragweed season.
House Dust Mite Allergen Extract (ODACTRA)	12 SQ-HDM tablet	12 to 65 yo	Start anytime and once daily administration until discontinued by provider.
Abbreviations: Amb a = Ambrosia artemisiifolia (short ragweed); BAUs = Bioequivalent Allergy Units; FDA = Food and Drug Administration; SQ-HDM = Standardized-Quality House Dust Mite units; IR = Index of Reactivity; SL = sublingual; yo = years old			

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for an FDA-approved indication?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is the request for continuation of current therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4

Approval Criteria		
4. Is the request for house dust mite immunotherapy (e.g., Odactra) and does the patient have co-morbid conditions funded by the OHP and listed in HERC guidance? • Uncontrolled Mild to Moderate Asthma Note: sublingual immunotherapy for grass and ragweed have insufficient evidence of benefit in allergic rhinitis and comorbid asthma	**Yes:** Go to #6	**No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP If eligible for EPSDT review: Go to #5
5. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	**Yes**: Go to #7	**No**: Pass to RPh. Deny; medical necessity.
6. If the patient has asthma, have they tried and failed to receive adequate benefit from or have a contradiction to a low to high dose orally inhaled corticosteroid treatment?	**Yes**: Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. Has the patient tried and failed to receive adequate benefit from or have a contraindication to oral antihistamines and/or nasal corticosteroids to manage allergic rhinitis?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical necessity.
8. Does the patient meet the FDA-approved age range outlined in **Table 1**?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. Is the request by, or in consultation with, an allergist or immunologist?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness
10. Does the patient have severe, unstable, or uncontrolled asthma, a history of eosinophilic esophagitis, or other severe systemic allergic reaction?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #11
11. Has the patient undergone a properly performed skin test and/or is there serologic evidence of IgE-mediated antibody to a potent extract of the allergen?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
12. Does the patient have a prescription on file for an epinephrine autoinjector in case of an adverse event?	**Yes:** Go to #13	**No:** Pass to RPh. Deny; medical appropriateness.
13. Will the first dose be administered under medical supervision?	**Yes**: Approve for 12 months.	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Does the provider attest that patient's symptoms have improved with sublingual immunotherapy treatment and not experienced any adverse effects?	**Yes**: Approve for 12 months.	**No:** Pass to RPh. Deny; medical appropriateness.

P&T/DUR Review: 8/23 (DM)
Implementation: 9/1/23